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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,054	02/11/2002	Siu-Yin Wong	273102008104	9080

7590

07/23/2003

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EXAMINER

CHIN, CHRISTOPHER L

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 07/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/074,054

Applicant(s)
Wong et al

Examiner
Chris Chin

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1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 11, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the desiccant material must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 U.S.C. § 112

2. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is vague and indefinite. Claim 26 is a Jepson type claim. Thus, the preamble of the claim must recite a detailed description of the prior art device. However, the preamble of claim 26 fails to provide a detailed description of the prior art immunoassay device. The preamble only sets forth a housing with an opening and an immunological reagent in dried form in the housing.

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Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claim 26 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,763,262. Although the conflicting claims are not identical, they are not patentably distinct from each other because patent '262 claims an immunoassay device with essentially the same limitations as the instantly claimed immunoassay device. Claim 1 of patent '262 recites an immunoassay device comprising a housing

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with an opening, a web of porous material with an immunological reagent in dried form in the housing, and a desiccant which is also in the housing.

The device of patent '262 differs from the instantly claimed device in reciting a web of porous material in the housing which is not recited in the device of instant claim 26.

However, it would have been obvious to one of ordinary skill in the art that the instant device is obvious over the device of patent '262 because the open broader claim language of instant claim 26 does not exclude the presence of a web of porous material in the housing of the instantly claimed device.

Claim Rejections - 35 U.S.C. § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tom et al in view of Svoboda et al and Thomas et al.

Tom et al (U.S. Patent 4,366,241) discloses an immunoassay device. The device provides for a narrow zone through which relatively large amounts of fluid pass with relatively uniform flow. The narrow zone serves to concentrate both a small amount of analyte in a sample, as well

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as, reagents for producing a detectible signal, while inhibiting the localization of non-specifically bound materials which would result in production of background signal unrelated to the amount of analyte in a sample (see col. 3, lines 4-55). As shown in the figures, the device comprises a housing (12) or (62) with openings (56) and (60) that allow for entry of a sample solution. Immunosorbing disks (64) and (66) reside directly under openings (56) and (60). Disk (64) has antibodies immobilized on its surface while disk (66) has antigen immobilized on its surface (see col. 17, line 48, to col. 18, line 44).

Svoboda et al (U.S. Patent 4,017,261) discloses diagnostic test strips for qualitative detection and semi-quantitative estimation of blood and hemoglobin in biological products. The test strips include a test area which contains reagents for detection of hemoglobin (col. 1, lines 5-54). In order to preclude deterioration prior to use of the test strips, Svoboda et al teach that it has been found useful to store the test strips in closed containers in the presence of a desiccant, such as silica or a molecular sieve (col. 4, lines 56-59).

Thomas et al (U.S. Patent 4,330,627) disclose a test tray for use in performing series of tests on a liquid specimen. The tray includes a base (12) to which a lid or cover member (14) is pivotly connected. Formed in the base (12) are a plurality of u-shaped closed bottom channels (16). Each channel (16) has an entry segment/port (18) and a test conducting segment (20). To close the test conducting segment (20) of each test channel, there is a sheet of clear plastic material (22) which is affixed to the upper surface of base (12) (col. 2, lines 33-64). A desiccant (26) is also part of the tray for absorbing moisture from the air in the tray (col. 3, lines 1-6 and

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col. 5, lines 3-18). Each of the channels (16) contain at least two reagent impregnated disks. The reagents on the disks are for the detection of microorganisms and their choice are governed by the specific test that is being performed (col. 3, lines 7-49).

It would have been obvious to one of ordinary skill in the art to include a desiccant in the housing of the immunoassay device of Tom et al, as taught by Thomas et al, because Svoboda et al teach that a desiccant would provide the advantage of retarding deterioration of reagent containing test strips prior to their use.

7. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al in view of Tom et al.

See above for the teachings of Thomas et al. The base (12) and cover (22) form a housing with an opening for entry of a liquid sample.

The tray of Thomas et al differs from the instant invention in failing to specifically teach the use of immunological reagents in the reagent disks for detection of microorganisms.

See above for the teachings of Tom et al. Tom et al teach using the disclosed device for assaying for the presence of microorganisms (col. 22, lines 34-68, and cols. 23-24).

It would have been obvious to one of ordinary skill in the art to use the immunological reagents for detection of microorganisms of Tom et al in the reagent disks in the tray of Thomas et al because Thomas et al teach using the tray for detection of microorganisms and Thomas et al does not place any limitations on what reagents can be used in the reagent disks. Moreover, the

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antibodies taught by Tom et al are highly specific binding reagents which provide the advantage of a more sensitive tray for detection of microorganisms.

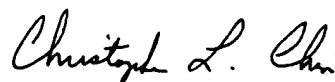
Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can normally be reached on Monday-Thursday from 10:00 am to 7:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

cchin/cc
July 22, 2003



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641